The supply of plasma-derived medicinal products in the future of Europe

Second edition

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CENTRO NAZIONALE SANGUE

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EU SoHO Regulation: EDQM Perspectives

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EDQM of the Council of Europe

I have no conflicts of interests to disclose for this presentation.

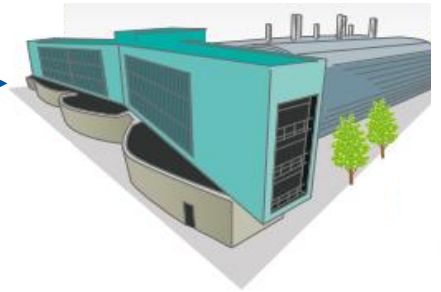
EDQM - a Directorate of the COUNCIL OF EUROPE

COUNCIL OF EUROPE

- Founded in **1949**
- **Intergovernmental** organisation, Strasbourg
- **46** Member States
- More than **700 Million** of Citizens

COMMITTEE OF MINISTERS | PARLIAMENTARY ASSEMBLY | CONGRESS OF LOCAL AND REGIONAL AUTHORITIES | EUROPEAN COURT OF HUMAN RIGHTS | COMMISSIONER OF HUMAN RIGHTS | CONFERENCE OF INGOS

The **European Directorate for the Quality of Medicines & HealthCare** (EDQM)



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European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

- Founded in 1964
- Work in the framework of a **Partial Agreement, 39 Members & the EU**
- Contribute to **Public Health and access to good quality medicines and healthcare in Europe**

EDQM and European Union - Cooperation SoHO

European Union & its bodies
- **European Commission**
- **European Medicines Agency**
- **European Centre for Disease Control and Prevention**

EUROPEAN UNION

The **European Directorate for the Quality of Medicines & HealthCare** (EDQM)

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COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

- Address risks emerging in SoHO through its mandate to set high standards of quality and safety of SoHO, in accordance with Art. 168(4)(a) of the Treaty on the functioning of the EU
- Drafting legislation and developing guidance, assisting national authorities with its implementation, conducting vigilance activities and supporting projects

- **Political dialogue**
- **Mutual representation**
- **Technical co-operation**
- **Legal/regulatory co-operation**

COMMON GOAL:
TO PROTECT CITIZENS

- Leading standard-setting organisation in the field of SoHO
- Develops legally binding texts (Conventions) and non legally binding texts (recommendations, resolutions, technical guides, reports and other publications)

EDQM - Blood Transfusion

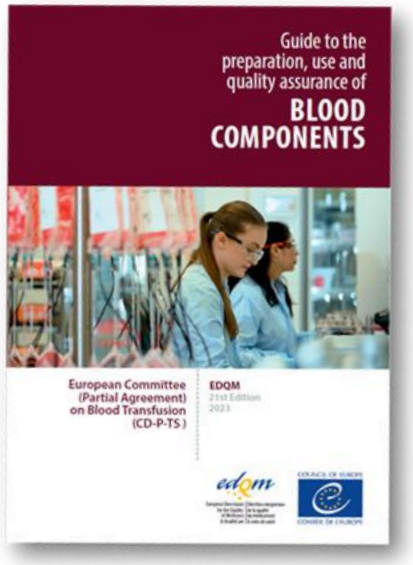
European Committee on Blood Transfusion (CD-P-TS)

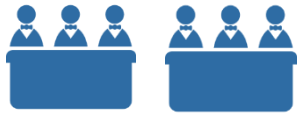
VNRBD

Mutual assistance

Protection of donors & the recipients

1. Developing legal instruments, technical standards, policies





Working Groups

2. Monitoring data and best practices

3. Operational activities supporting BEs implementing technical standards & EU legislation

Funded by the European Union and the Council of Europe
EUROPEAN UNION
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE
Implemented by the Council of Europe

EDQM - Plasma Supply Management Symposium

Jointly organised by EU Commission and EDQM – 29th and 30th Jan 2019

Focus:

- *Discuss obstacles in Europe to strategic independence of plasma for fractionation in Europe*
- *Discuss donor protection – safety, selection and management*
- *Presenting evidence based data for revision of Blood Guide chapter 2 plasmapheresis donors;*

Attended by 150 participants from 33 countries

www.edqm.eu/en/projects

EDQM & EU Commission
Plasma Supply Management Symposium
(29-30 January 2019)

Recommendations to Stakeholders

These recommendations were drafted by a working group consisting of members of the TS093 Plasma Supply Management Working Group, a subordinate working group of the European Committee on Blood Transfusion (CD-P-TS), and stakeholders' representatives during a meeting held the day after the Plasma Supply Management Symposium (list of participants as Appendix).

EU Commission
EDQM/CD-P-TS
Member States National Competent Authorities
Blood Establishments
Plasma Fractionators
Patient Associations
Donor Associations
Professional Societies

Blood Guide- Plasma

21st Edition of the Blood Guide – Published April 2023

B-GPG

Chapter 1
General notices

Chapters 2-4 & 7-11

Chapter 5 & 6
Monographs

Appendices

Commission Directive (EU) 2016/1214 – "*Member states shall ensure that blood establishments take fully into account the standards and specifications set out in those guidelines when implementing their quality system"* The GPG are an integral part of the Blood Guide and revised/updated alongside"

Chapter 2 - Donor Selection

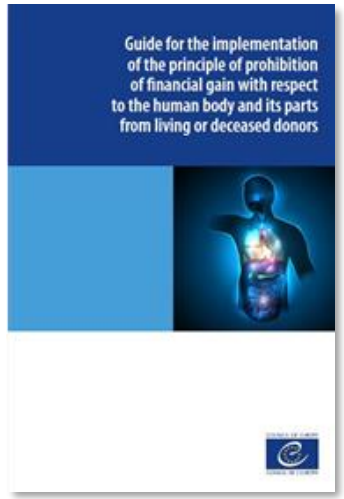
Chapter 3 – Collection of Blood and Blood Components

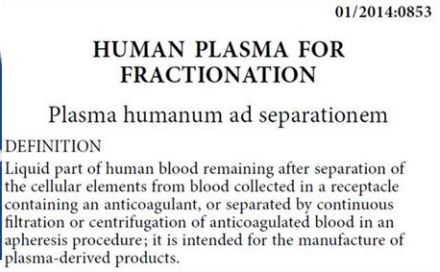
Chapter 9 – Screening

Chapter 10 – Haemovigilance

36 Monographs – Whole Blood, Red Cell, Platelet, Plasma and White Cell Components, Intrauterine, neonatal and infant use;

4 appendices (Donor Eligibility, SPC, tables for calculation of blood/collection volumes, health economics)

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HUMAN PLASMA FOR FRACTIONATION

Plasma humanum ad separationem

DEFINITION

Liquid part of human blood remaining after separation of the cellular elements from blood collected in a receptacle containing an anticoagulant, or separated by continuous filtration or centrifugation of anticoagulated blood in an apheresis procedure; it is intended for the manufacture of plasma-derived products.

EU SoHO Regulation

THE KEY MEASURES

STRENGTHENED LEVELS OF HEALTH PROTECTION

A wider scope to cover blood, tissues, and cells, together with other SoHO (like human breast milk or faecal microbiota)

High standards for safety and quality, implemented through **technical guidelines** developed mostly by expert bodies[1] based on up-to-date scientific evidence

Renewed commitment to the **principle of voluntary and unpaid donation**, protecting donors from exploitation and from risks to their own health without discouraging donations

Improved reporting and follow-up on adverse reactions

FACILITATION OF INNOVATION

Common EU-wide authorisation procedures for innovative SoHO preparations

Body providing advice on regulatory status of a substance or a product

HARMONISATION, SIMPLIFICATION & SUPPORT

Implementation of risk-based oversight, for more efficient use of resources (for authorising establishments and activities, carrying out of inspections...)

Application of **common technical guidelines** while safeguarding Member States' possibility to have more stringent rules

Collection of information on supply, quality and safety of SoHO for oversight, policy and research

EU support to Member States through training for authorities, joint activities and advisory mechanism

DIGITALISATION

Common IT Platform to facilitate data reporting and information sharing

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EDQM – Expert Body

Technical Guidelines – Means to demonstrate compliance with the Regulation

Legislative cascade

- Quality Management
- Donor and Recipient Protection Standards – *"Other than from transmission of communicable diseases"*
- Monographs (PPA)
- Emergency Planning

EDQM – Ongoing Work

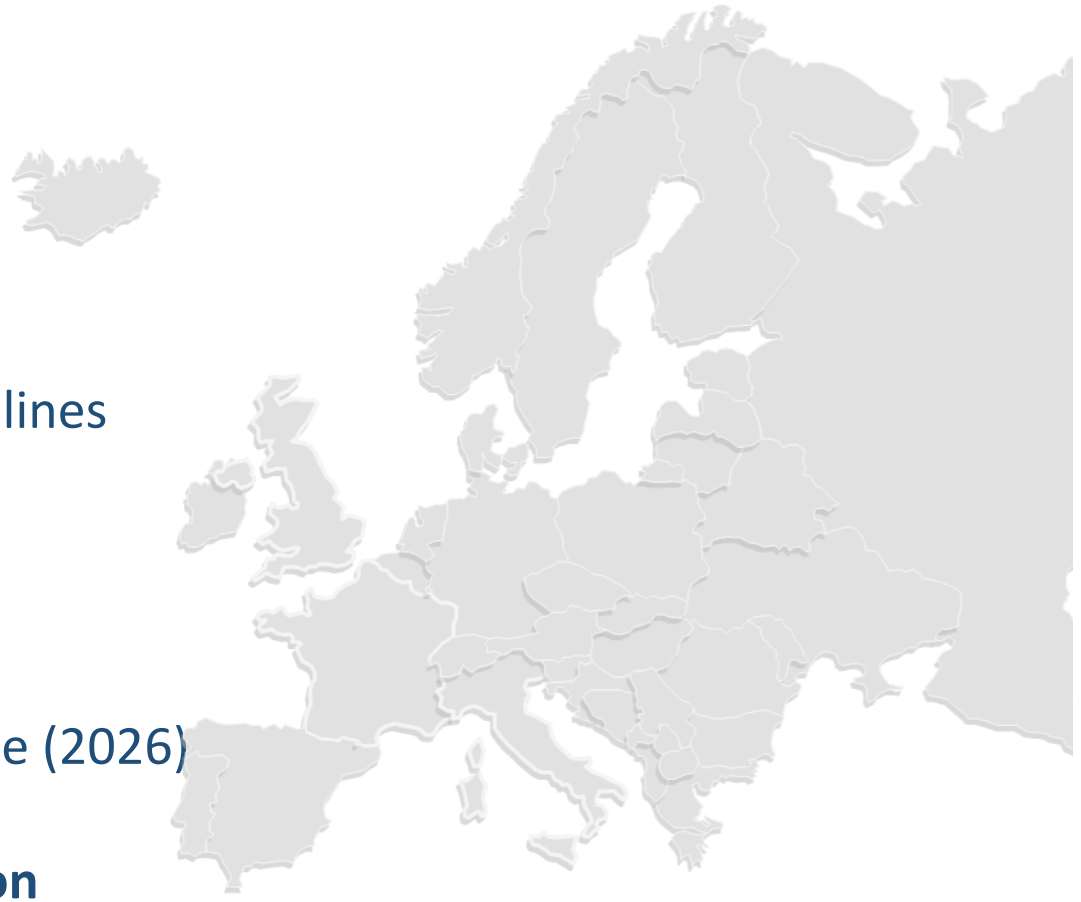
22nd Edition of Blood Guide
Consultation - May and June 2024
Adoption – November 2024
Publication – March 2025

Preparation for EU SoHO Regulation
Mapping over standards – EU Regulation vs Technical Guidelines
Existing Directive references
Scientific Evidence

Improvement of Processes
Digitalisation Project – Consultation (2025) and Online Guide (2026)

European Commission / ECDC / EMA / EDQM – Cooperation

Stakeholder Engagement



EDQM – Plasma

CD-P-TS under the coordination of the EDQM will continue;

- The Blood Guide revision (evidence-based criteria)
- Data Collection and Reporting
- Support the coordination of meetings concerning immunoglobulin (IgG) use and rare disease treatment (Kreuth Symposium – Expected 2025)
- Plasma collection-targeted activities

Continue to help strengthen the implementation of measures to promote and support safe plasma donation and donor protection, and to ensure continued and safe access for patients to plasma-derived medicinal products for life-saving treatments

Thank you